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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,655	12/20/2001	Rodolfo A. Padua	P-9406.00	1152

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MEDTRONIC, INC.
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EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,655	PADUA ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *on 04/05/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-26,39,40 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-26,39,40 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

2. Claims 41 and 42 have been cancelled. Claims 5, 6, and 27-38 have been withdrawn. Claims 1, 39, 40, 43, and 44 have been amended. New claims 45-48 have been added. No new matter was introduced by the amendments or by addition of the new claims.

Claims 1-4, 7-26, 39, 40, 43-48 are pending and under examination.

Response to Amendment

The amendment to the claims filed on 04/05/2006 does not comply with the requirements of 37 CFR 1.121(c) because the Applicants indicate the status of "original" for the amended claim 43. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression:

(Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Applicants are required to indicate the correct "currently amended status for claim 43.

Response to Arguments

Specification

3. The objection to claims 41 and 44 under 37CFR 1.75(c), as being of improper dependent form is withdrawn in response to Applicants cancellation of claim 41 and amendment to claim 44 filed on 04/05/2006.

Claim Rejections - 35 USC § 112 – enablement

4. The rejection of claims 41 and 42 under 35 USC § 112 first paragraph, as not meeting the enablement requirement, is withdrawn in response to Applicants' cancellation of the claims.

5. Claims 1-4, 7-26, 39, 43, and 44 remain rejected and new claims 45-47 are rejected under 35 USC § 112 first paragraph as not being enabled for (i) a therapeutic delivery system comprising an implanted electrical pulse generator operably coupled with genetically engineered cells that have been transplanted into a mammalian tissue, wherein said genetically engineered cells further comprise a target gene that has been operably coupled *in vitro* to a heterologous electrically responsive promoter capable of enhancing transcription of said target gene (claims 1-4, 7-26, and 43) and (ii) a method of treating a patient comprising providing the patient with an implantable electrical pulse generator operably coupled with genetically engineered cells that have been transplanted into a patient tissue, wherein said genetically engineered cells further comprise a target gene operably coupled *in vitro* to a heterologous electrically

responsive promoter capable of enhancing transcription of said target gene (claims 39, and 45-48), for the reasons of record set forth in the prior Office Action.

Applicant's arguments filed 04/05/2006 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that they submitted a series of amendments to the independent claims 1 and 39. More specifically, the claims were amended to recite that (i) the genetically engineered cells comprise the target gene operably coupled *in vitro* to an electrically responsive promoter, (ii) the electrical pulse generator is implanted, (iii) the genetically engineered cells are implanted in a mammalian tissue, (iv) the system is capable of enhancing transcription, and (v) the electrically responsive promoter is a heterologous promoter. Applicants argue that the Examiner stated that the application was enabled under these conditions and. Therefore, Applicants request the withdrawal of the rejection.

Contrary to Applicants assertion, the amendments to claim 1 and 39 are not sufficient to overcome the enablement rejection of the instant claims for several reasons.

First, what the Examiner stated was that the instant claims are only enabled for **(i)** electrically stimulated induction of gene expression *in vitro* using an electrical pulse generator operably coupled with cultured genetically engineered cells comprising a target gene operably coupled to an electrically responsive promoter (i.e., *in vitro* induction of gene expression by electrical stimulation using an electrical pulse generator operably coupled with cultured genetically engineered cells comprising a target gene operably coupled to an electrically responsive promoter) and **(ii)** delivering to a subject

an electrical pulse generator operably coupled to genetically engineered cells, wherein genetically engineered cells are transplanted into the subject **and not** for the treatment of a patient. Although they were amended, claims 1-4, 7-26, and 43 are still drawn to a therapeutic delivery system, and therefore the amendments to the claims are not enough to overcome the instant rejection. Such language directed to a therapeutic delivery system is considered to directly embrace administering to animals a therapeutic agent in an amount sufficient such that the treatment of an animal having a condition associated with the therapeutic agent is achieved. Accordingly, preamble language directed to "therapeutic delivery system" is considered to require support as outlined in 35 U.S.C. § 112 first paragraph such that therapeutic benefit is considered to be enabled for one seeking to make and use such a delivery system. Similarly, claims 39, and 43 and new claims 45-47 are still drawn to a method of treating a patient by using the therapeutic delivery system. Claims 1-4, 7-26, 39, 40, and 43 are not enabled for the treatment of a patient because issues with the breadth of the claims (the range of diseases to be treated, the range of therapeutic agents, and the range of genetically modified cells), with the unpredictability of the outcome of the treatment, with prolonged and/or controlled expression of the therapeutic gene in a sufficient amount to result in a therapeutic effect, and with the lack of guidance and working examples still remain (see the prior Office Action). The same applies to the new claims 45-47, which are dependent on claim 39.

Second, amending the claims to recite that the genetically engineered cells comprise "a target gene that has been operably coupled *in vitro* to a heterologous

electrically responsive promoter" means only that the construct was recombinantly made *in vitro*. Therefore, the genetically engineered cells can be obtained either *in vitro* by transfecting them with the recombinant construct before transplantation, or *in vivo* by transfecting the pre-transplanted cells via the delivery of the construct to the mammal. As a consequence, issues such as unpredictability of the efficacy of delivering the construct to the targeted cells (i.e., delivery systems, specific delivery to the desired cells, and target accessibility) still exist (see prior Office Action).

Given the diverse and unpredictable outcome of using the disclosed delivery system to treat diseases, the specification does not appear to provide sufficient guidance and/or working examples that specifically address the use of this delivery system as being effective in treating various diseases in animals to enable one of ordinary skill in the art to use such delivery system without undue experimentation.

In conclusion, the presently claimed invention only provides enough of a disclosure to allow for an Artisan to: (i) electrically stimulate, *in vitro* (i.e., in tissue culture), induction of gene expression using an electrical pulse generator operably coupled with cultured genetically engineered cells comprising a target gene operably coupled to an electrically responsive promoter and (ii) delivering to a subject an electrical pulse generator operably coupled to genetically engineered cells, wherein genetically engineered cells are obtained *in vitro* and then transplanted into the subject.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1-4, 11, 23, 24, and 44 under 35 USC § 102(b) as being anticipated by Gilmour et al. (Developmental Biology, 1995, 268: 416-428) is withdrawn in response to Applicants amendments to claim 1, filed on 04/05/2006.

7. The rejection of claims 1-4, 11, 13, 23, 24, and 44 under 35 USC § 102(b) as being anticipated by Yanagida et al. (Journal of Biotechnology, April 14, 2000, 79: 53-61) is withdrawn in response to Applicants amendments to claim 1, filed on 04/05/2006.

Claim Rejections - 35 USC § 103

8. The rejection of claims 41 and 42 under 35 USC § 103(a) as being unpatentable over Lee et al. (Circulation, Aug, 22, 2000, 102: 898-901), in view of Kanno et al. (Circulation, 1999, 99: 1682-1687) is withdrawn in response to Applicants cancellation of the claims on 04/05/2006.

New Rejections

Specification

9. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 recites "a therapeutic delivery system of claim 1 wherein the electrical pulse generator is

external". However claim 1 is drawn to an implanted electrical pulse generator and does not disclose an external electrical pulse generator.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-4, 7-10, 13, 14, 23-25, 39, 40, and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Circulation, Aug, 22, 2000, 102: 898-901), in view of both Kanno et al. (Circulation, 1999, 99: 1682-1687) and Pahwa et al. (Neurology, 1997, 49: 249-253).

Lee et al. teach implantation of primary murine myoblasts expressing the murine VEGF gene from a retroviral promoter into the ventricular wall of immunodefficient mice (Abstract, p. 899, column 1, Materials and Methods). Lee et al. teach that uncontrolled VEGF expression from the implanted VEGF-expressing skeletal muscle myoblasts results in the formation of hemangiomas and therefore, a regulated VEGF expression is needed for a successful therapy (p. p. 898, column 2 bridging p. 899, p. 900, column 2, last paragraph). Lee et al. do not specifically teach an electrically responsive promoter or induction of VEGF by electrical stimulation. Kanno et al. teach induction of VEGF in electrical pulse stimulated murine myoblast cell line C2C12, i.e., the VEGF gene

comprises an electrically responsive promoter (p. 1682, column 2, Methods, and p.2684, column 2, second and third paragraphs). The pulses do not appear to damage the cells and thus, are considered to be sub-threshold- or threshold-applied pulses. Kanno et al. teach that gene therapy using VEGF is relevant for therapeutic angiogenesis and that localized electrical stimulation could force cells in the ischemic area to synthesize an adequate amount of VEGF to salvage the ischemic area (Abstract, p. 2686, column 2, last paragraph). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to modify the procedure of Lee et al. and increase VEGF expression by generating an electrical pulse, as taught by Kanno et al., with a reasonable expectation of success. The motivation to do so is provided by Kanno et al. who teach gene therapy as relevant for therapeutic angiogenesis and the importance of localized, controlled expression of VEGF induced by electrical pulse stimulation that can promote the activity of the promoter which would activate local VEGF production, salvaging the ischemic area (Abstract, and p. 2686, column 2, last paragraph) and by Lee et al. who teach potential toxicity of unregulated myoblasts-mediated VEGF expression (p. 900, column 2, last paragraph). Either Lee et al. or Kanno et al. do not explicitly teach the limitation of using an implanted pulse generator operably coupled with the VEGF-expressing myoblasts as to provide an electrical pulse for gene expression in these cells. However, at the time the invention was made, Pahwa et al. did teach that electrical pulse generators could be implanted to stimulate a targeted tissue and that they can be externally controlled by computers (Abstract, p. 250, column 2, p. 251, column 1). Thus, it would have been obvious to one

of ordinary skill in the art to employ such devices for providing a desired amount of pulses to the targeted tissue (i.e., the genetically engineered implanted myoblasts) as taught by the primary reference, e.g., Lee et al. or Kanno et al. One of ordinary skill in the art would have been motivated to employ a pulse making device such as an implanted or external pace maker or pulse generator because such devices are well known in the art and the use of the device would provide the sources of pulses as required for providing a stimulation of gene expression, which electrical pulse stimulation of a promoter is crucial for modulation of gene expression as taught by the primary reference. One of ordinary skill in the art would have a reasonable expectation of success in making and use such as the combined composition because medical devices such as implantable pulse generators or pace makers are proven to provide any amount of pulses as desired in stimulating gene expression. With respect to the limitation of a heterologous electrically responsive promoter, absent evidence of unexpected results, if the general conditions of a given method are disclosed in the prior art, it would have been obvious to the ordinary skilled artisan to vary the parameters in a given method (i.e., replace the VEGF electrically responsive promoter with a heterologous one) with the aim of optimizing the results. Again, absent evidence to the contrary, it is generally not inventive to substitute equivalents known for the same purpose, such substitutions can be done by routine experimentation. The following is a citation from MPEP:

2144.06 Art Recognized Equivalence for the Same Purpose

SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); *In re Scott*, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); *Smith v. Hayashi*, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. 'This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).
An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Foust*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

12. Claims 1-4, 7-25, 39, 40, and 43-48 are rejected under 35 USC 103(a) as being unpatentable over Lee et al., taken with Kanno et al. and Pahwa et al., as applied to claim 1-4, 7-10, 13, 14, 23-25, 39, 40, and 43-48, in view of both McDonough et al. (J. Biol Chem, 1997, 272: 24046-24053) and Allen (Ann Thorac Surg, 1999, 68: 1924-1925).

Lee et al., taken with Kanno et al. and Pahwa et al. do not teach the limitation of using an electrically enhancer element selected from the ANF 5' non-coding region. However, at the time the invention was made, McDonough et al. did teach elements

derived from the ANF 5' non-coding region driving the expression of the luciferase gene upon electrical stimulation (page 24047, Experimental Procedures). Thus, it would have been obvious for one of ordinary skill in the art, at the time the invention was made, to replace the VEGF enhancer with the enhancer of McDonough et al. (i.e., the enhancer element is heterologous to the coding sequence or to the promoter sequence) with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to employ such a chimeric enhancer-promoter containing in conjunction with an electrical pulse generator for controlled delivery of genes, and would have been expected to have a reasonable expectation of success in making and use such as the combined composition because the enhancer element selected from the ANF 5' non-coding region is proven to promote gene expression as desired, upon electrical stimulation.

Lee et al., taken with Kanno et al. and Pahwa et al. do not teach the limitation of a tissue specific promoter. However, at the time the invention was made, Allen did teach organ-selective local delivery of therapeutic genes (Abstract, page 1924 bridging page 1925, column 1, first paragraph). Thus, it would have been obvious for one of ordinary skill in the art, at the time the invention was made, to genetically alter cells with a construct comprising the VEGF electrically responsive enhancer and link it to a tissue specific promoter for local delivery, as taught by Allen, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to employ such a chimeric enhancer-promoter construct in conjunction with an electrical pulse generator for controlled delivery of genes to specific organs/tissue, since the electrical pulse

stimulation of a promoter is crucial for modulation of gene expression as taught by the primary reference. One of ordinary skill in the art would have a reasonable expectation of success in making and use such as the combined composition because electrically responsive enhancers are proven to promote gene expression as desired, upon electrical stimulation.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

13. Claims 1-4, 7-10, 13, 14, 23-26, 39, 40, and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. taken with Kanno et al. and Pahwa et al., as applied to claims 1-4, 7-10, 13, 14, 23-25, 39, 40, and 43-48 above, in further view of Kaye et al. (Circ Res, 1996, 78: 217-224).

Lee et al. taken with Kanno et al. and Pahwa et al. do not teach a coding sequence selected from the group recited in claim 26. However, at the time the invention was made, Kaye et al. did teach activation of constitutive nitric oxide synthase (NOS) in rat myocytes upon electrical stimulation (Abstract, page 219, bridging page220, column 1). Thus, it would have been obvious for one of ordinary skill in the art, at the time the invention was made, to employ a genetically engineer a cell with a construct comprising the VEGF linked to a cDNA encoding for NOS to modulate NOS expression upon electrical stimulation, with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to employ such a chimeric construct in conjunction with an electrical pulse generator for controlled

expression of NOS, since Kaye et al. teach that NOS participates in the regulation of contractile function of cardiac muscle via nitric oxide synthesis, which in turn mediates muscarinic cholinergic signaling in cardiac myocytes and specialized pacemaker tissue, and modifies contractile response to β-adrenergic stimulation (page 217 bridging page 218). One of ordinary skill in the art would have been expected to have a reasonable expectation of success in making and use such as the combined composition because the VEGF promoter is proven to modulate gene expression as desired, upon electrical stimulation.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER

Ileana Popa